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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Marc Feldmann and Ravinder N. Maini
Serial No. : 09/921,937 Examiner: **Not yet known**
Filed : August 3, 2001 Group Art Unit: Not yet known
For : ANTI-TNF ANTIBODIES AND METHOTREXATE IN THE
TREATMENT OF AUTOIMMUNE DISEASE

1185 Avenue of the Americas
New York, New York 10036
June 20, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicants submit herewith an Information Disclosure Statement under 37 C.F.R. §1.56.

In accordance with their duty of disclosure under 37 C.F.R. §1.56 and 37 C.F.R. §1.97(a)-(b)(2), applicants would like to direct the Examiner's attention to the following publications which are listed on the attached Form PTO-1449 (**Exhibit A**). Copies of cited publications 4, 6-10, 19-25, 27, 30, 32, 33, 35-37, 39-43, 45, 48 and 49 are attached hereto as **Exhibits 1-28**, respectively. Publications 1, 2, 11-13, 14-18, 28, 29, 31, 44 and 47 were entered in prior application U.S. Application No. 07/958,248, filed October 6, 1993, to which priority under 35 U.S.C. §120 is claimed. Publications 3, 5, 26, 38 and 46 were entered in prior application U.S. Application No. 08/607,419, filed February 28, 1996, to which

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priority under 35 U.S.C. §120 is claimed. Publication 34 was entered in prior application U.S. Application No. 08/690,775, filed August 1, 1996, now U.S. Patent No. 6,270,766, issued August 7, 2001, to which priority under 35 U.S.C. §120 is claimed. According to 37 C.F.R. §1.98(d), copies of patents or publications that were previously cited by, or submitted to, the Office in connection with such prior applications need not accompany the Information Disclosure Statement.

This Supplemental Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b)(3) before the mailing of a first Office Action on the merits. Thus, this Information Disclosure Statement should be entered and considered.

1. U.S. Patent No. 5,096,906, issued March 17, 1992, Mandell, et al.;
2. U.S. Patent No. 4,695,459, issued September 22, 1987, Steinman, et al.;
3. U.S. Patent No. 5,502,066, issued March 26, 1996, Heinemann, et al.;
4. U.S. Patent No. 5,658,570, issued August 19, 1997, Newman, et al. (**Exhibit 1**);
5. U.S. Patent No. 5,580,873, issued December 3, 1996, Bianco, et al.;

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6. U.S. Patent No. 5,298,396, issued March 29, 1994, Kotzin, et al. (**Exhibit 2**);
7. U.S. Patent No. 5,468,481, issued November 21, 1995, Sharma, et al. (**Exhibit 3**);
8. U.S. Patent No. 5,260,422, issued November 9, 1993, Clark, et al. (**Exhibit 4**);
9. U.S. Patent No. 5,204,329, issued April 20, 1993, Ackerman, et al. (**Exhibit 5**);
10. U.S. Patent No. 5,994,510, issued November 30, 1999, Adair, et al. (**Exhibit 6**);
11. PCT International Application Publication No. WO 92/07076, published April 30, 1992;
12. PCT International Application Publication No. WO 91/10722, published July 25, 1991;
13. PCT International Application Publication No. WO 90/15152, published December 13, 1990;
14. European Patent Application No. EP 0 240 344, published October 7, 1987;
15. Australian Patent Application No. AS 58976/90, published September 22, 1987;

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16. Canadian Patent No. 2,021,369, issued January 19, 1991;
17. German Patent No. DE 40 06 269 A1, issued February 28, 1990;
18. British Patent Application No. GB 2 246 569 A, published June 15, 1990;
19. Arend, W.P., et al. (1990) Arthritis Rheum. 33(3):305-315
(Exhibit 7);
20. Bach, J.F. (1993) TiPs 14:213-216 (Exhibit 8);
21. Barrera, P., et al. (1995) Br. J. Rheumatol. 34:747-755
(Exhibit 9);
22. Brennan, et al. (1994) Clin. Exp. Immunol. 97:1-3 (Exhibit 10);
23. Cooper, K.D. (1993) Clin. Rev. Allergy 11:543-559 (Exhibit 11);
24. Elliott, M.J., et al. (1994) Int. Arch. Allergy Immunol. 104:112-125 (Exhibit 12);
25. Feldmann, M., et al. (1996) Ann. Rev. Immunol. 14:397-440
(Exhibit 13);
26. Flesch (1992) Blood 79:3366-3368;

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27. Fries, J.F., et al. (1990) J. Rheumatol. 17(22):12-15 (**Exhibit 14**);
28. Genzyme Catalog (1991) pp. 79-80;
29. Harris, et al. (1993) Tibtech 11:42-44;
30. Herzog, C., et al. (1987) Lancet 2(8573):1461-1462 (**Exhibit 15**);
31. Hozzof, et al. (1987) Lancet 11:1461-1642;
32. Kahan, B.D. (1992) Curr. Opin. Immunol. 4:553-560 (**Exhibit 16**);
33. Littman, B.H., et al. (1995) Arthritis Rheum. 38:29-37 (**Exhibit 17**);
34. Maini, R.N. (1996) J. Royal College of Physicians of London 30(4):344-351;
35. Matsumiya, G., et al. (1996) Transplant Proceed. 28(2):751-753 (**Exhibit 18**);
36. Moreland, L.W., et al. (1995) Arthritis Rheum. 38:1581-1588 (**Exhibit 19**);
37. Moreland, L.W., et al. (1996) J. Rheumatol. (Supplemental 44) 23:78-83 (**Exhibit 20**);

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38. Piguet, et al. (1992) Immunology 77:510-514;
39. Qin, S., et al. (1987) Eur. J. Immunol. 17:1159-1165 (**Exhibit 21**);
40. Richardson, C., et al. (1995) Br. J. Clin. Prac. 49:135-139 (**Exhibit 22**);
41. Sander, O., et al. (1995) Arthritis Rheum. 38:S266 (Abstract 678) (**Exhibit 23**);
42. Sosman, J.A., et al. (1993) J. Pediatric Hematol. Oncol. 15(2):185-195 (**Exhibit 24**);
43. Stein, C.M., et al. (1994) Arthritis Rheum. 37:S252 (**Exhibit 25**);
44. Strober, et al. (1990) Immunol. Reviews 118:233-255;
45. Stuart, et al. (1986) Laboratory Investigation 54:1-3 (**Exhibit 26**);
46. Thorbecke, et al. (1992) Proc. Natl. Acad. Sci. USA 85:7375-7379;
47. Waldmann, T.A. (1991) Science 252:1657-1662;
48. Weinblatt, M.E., et al. (1994) Arthritis Rheum. 37:1492-1498 (**Exhibit 27**); and

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49. Decision on Appeal, issued March 21, 2003, for U.S. Serial No. 09/093,458, filed June 8, 1998 (**Exhibit 28**).

Applicants request that the Examiner review the publications and make them of record in the subject application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

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Date

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INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Applicants: Marc Feldmann et al.

Filing Date
August 3, 2001

Group

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	5 0 9 6 9 0 6	3/17/92	Mandell, et al.;			
	4 6 9 5 4 5 9	9/22/87	Steinman, et al.;			
	5 5 0 2 0 6 6	3/26/96	Heinemann, et al.;			
	5 6 5 8 5 7 0	8/19/97	Newman, et al. (Exhibit 1);			
	5 5 8 0 8 7 3	12/3/96	Bianco, et al.;			
	5 2 9 8 3 9 6	3/29/94	Kotzin, et al. (Exhibit 2);			
	5 4 6 8 4 8 1	11/21/95	Sharma, et al. (Exhibit 3);			
	5 2 6 0 4 2 2	11/9/93	Clark, et al. (Exhibit 4);			
	5 2 0 4 3 2 9	4/20/93	Ackerman, et al. (Exhibit 5);			
	5 9 9 4 5 1 0	11/30/99	Adair, et al. (Exhibit 6);			

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
	WO 9 2 0 7 0 7 6	4/30/92	PCT;				
	WO 9 1 1 0 7 2 2	7/25/91	PCT;				
	WO 9 0 1 5 1 5 2	12/13/90	PCT;				
	EP 0 2 4 0 3 4 4	10/7/87	EPO;				
	AS 5 8 9 7 6 9 0	9/22/87	AS;				
	CN 2 0 2 1 3 6 9	1/19/91	CN;				
	DE 4 0 0 6 2 6 9	2/28/90	DE;				
	GB 2 2 4 6 5 6 9	6/15/90	GB;				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	Arend, W.P., et al. (1990) <u>Arthritis Rheum.</u> 33(3):305-315 (Exhibit 7);
	Bach, J.F. (1993) <u>TiPs</u> 14:213-216 (Exhibit 8);
	Barrera, P., et al. (1995) <u>Br. J. Rheumatol.</u> 34:747-755 (Exhibit 9);
	Brennan, et al. (1994) <u>Clin. Exp. Immunol.</u> 97:1-3 (Exhibit 10);
	Cooper, K.D. (1993) <u>Clin. Rev. Allergy</u> 11:543-559 (Exhibit 11);
	Elliott, M.J., et al. (1994) <u>Int. Arch. Allergy Immunol.</u> 104:112-125 (Exhibit 12);
	Feldmann, M., et al. (1996) <u>Ann. Rev. Immunol.</u> 14:397-440 (Exhibit 13);
	Flesch (1992) <u>Blood</u> 79:3366-3368;
	Fries, J.F., et al. (1990) <u>J. Rheumatol.</u> 17(22):12-15 (Exhibit 14);
	Genzyme Catalog (1991) pp. 79-80;

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Applicants: Marc Feldmann, et al.
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Exhibit A

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Harris, et al. (1993) Tibtech 11:42-44;Herzog, C., et al. (1987) Lancet 2(8573):1461-1462 (Exhibit 15); ✓Hozzof, et al. (1987) Lancet 11:1461-1642;Kahan, B.D. (1992) Curr. Opin. Immunol. 4:553-560 (Exhibit 16); ✓Littman, B.H., et al. (1995) Arthritis Rheum. 38:29-37 (Exhibit 17); ✓Maini, R.N. (1996) J. Royal College of Physicians of London 30(4):344-351;Matsumiya, G., et al. (1996) Transplant Proceed. 28(2):751-753 (Exhibit 18); ✓Moreland, L.W., et al. (1995) Arthritis Rheum. 38:1581-1588 (Exhibit 19); ✓Moreland, L.W., et al. (1996) J. Rheumatol. (Supplemental 44) 23:78-83 (Exhibit 20); ✓Piguet, et al. (1992) Immunology 77:510-514;Qin, S., et al. (1987) Eur. J. Immunol. 17:1159-1165 (Exhibit 21); ✓Richardson, C., et al. (1995) Br. J. Clin. Prac. 49:135-139 (Exhibit 22); ✓Sander, O., et al. (1995) Arthritis Rheum. 38:S266 (Abstract 678) (Exhibit 23); ✓Sosman, J.A., et al. (1993) J. Pediatric Hematol. Oncol. 15(2):185-195 (Exhibit 24); ✓Stein, C.M., et al. (1994) Arthritis Rheum. 37:S252 (Exhibit 25); ✓Strober, et al. (1990) Immunol. Reviews 118:233-255;Stuart, et al. (1986) Laboratory Investigation 34:1-13 (Exhibit 26); ✓Thorbecke, et al. (1992) Proc. Natl. Acad. Sci. USA 85:7375-7379;Waldmann, T.A. (1991) Science 252:1657-1662;Weinblatt, M.E., et al. (1994) Arthritis Rheum. 37:1492-1498 (Exhibit 27); and ✓

Decision on Appeal, issued March 21, 2003, for U.S. Serial No. 09/093,458, filed June 8, 1998 (Exhibit 28). ✓

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